MONTANA
Department of Public Health & Human Services

Screening Criteria for Botox Injections

Description:

Botox (Botulinum Toxin Type A) and Myobloc (Botulism Toxin Type B) are purified toxins produced by bacterium Clostridium botulinum. In small doses, it is injected into specific muscles at motor nerve endings. The therapeutic effect is evidenced by paralysis or reduced tone in specific muscles.

The U.S. Food and Drug Administration (FDA) has approved two of the seven botulinum types to treat specific conditions marked by involuntary muscle contractions: Type A (Botox) is approved to treat Blepharospasm, Strabismus, Facial Nerve (VII) Disorders and Cervical Dystonia. Myobloc (Type B) is approved for cervical dystonia.

Both Toxins are also used for a number of off-label indications. It is anticipated that botulinum type B (Myobloc) will be used for the same range of indications as botulinum type A (Botox).

The degree of relief and duration of effect varies from person to person but most patients experience adequate symptom relief for approximately three months. Patients can be treated indefinitely as long as there is continued adequate symptom relief and there are no adverse side effects.

The safety and effectiveness of using botulinum toxin for the treatment of blepharospasm or strabismus in children below the age of 12, or for the treatment of cervical dystonia below the age of 16, has not been established.

Botulinum toxin should not be used in pregnancy or with breastfeeding.

Coverage:

>Laryngeal spasm
>Blepharospasm
>Hemifacial spasm of the nerve
>Torticollis, unspecified
>Strabismus and other disorders of binocular eye movements
>Torsion dystonia
>Fragments of dystonia
>Hereditary spastic paraplegia
>Multiple Sclerosis
>Other demyelinating diseases of the central nervous system
>Spastic hemiplegia
>Infantile cerebral palsy
>Other specified infantile cerebral palsy

>Achalasia and cardiospasm
>Spasm of muscle
>Hyperhidrosis

Indications and Limitations of coverage and/or Medical Necessity

1. Before consideration of coverage may be made, it should be established that the patient has been unresponsive to conventional methods of treatment such as medication, physical therapy, and other appropriate methods used to control and/or treat spastic conditions

2. Coverage of Botulinum Toxin Type A for certain spastic conditions (e.g., cerebral palsy, stroke, head trauma, spinal cord injuries and multiple sclerosis) will be limited to those conditions listed in this policy. All other uses in the treatment of other types of spasm, including smooth muscle types, will be considered as investigational and therefore not covered by Medicaid.

3. Botulinum Toxin Type A can be used to reduce spasticity or excessive muscular contractions to relieve pain; to assist in posturing and walking; to allow better range of motion; to permit better physical therapy; to reduce severe spasm in order to provide adequate perineal hygiene.

4. Botox injections can be used to treat limb spasticity. Botox injections encompass different techniques, the number of injections made into each site or muscle, dosage, combination of muscles injected, etc. Dosage appears to vary from 1-25 units per small muscle (e.g., eye), 50-200 units for medium to larger muscle groups (e.g., deltoid, biceps, quadriceps, hamstrings, etc.) Dosage should be adjusted for youngsters.

   The degree of spasticity is also a deciding dose factor. Some recommended no more than 2-4 units/kgm body weight usually. Only 3-400 units are generally injected totally, up to 6-8 sites, into each limb. Some use even higher doses, up to 6-700 units for even more injection sites in select cases where toxicity is not a prime consideration. The failure of two injections in a row, using maximum dose for the size of the muscle, will preclude continued reimbursement. This could be altered initially, however, until a correct dose and site can be found.

   Failure after two successful treatments in a row for initial therapy, using maximum amounts, could preclude additional coverage. If failure occurs, injections could be repeated in a year.

5. Botox can also be used in the treatment of achalasia. It appears to be safe and effective. Two thirds respond within six months and effectiveness lasts an average of a little over one year for an initial treatment. Its use should not be endorsed for all patients but it can be considered individually in patients who:

- Have failed conventional therapy
- Are at high risk of complications of pneumatic dilation or surgical myotomy
- Have failed a prior myotomy or dilation
- Have had a previous dilation induced perforation
- Have an epiphrenic diverticulum or hiatal hernia, both of which increase the risk of dilation-induced perforation.

6. Some patients fail a first injection and respond to a second. Further therapy should be questioned if two treatments in a row fail. Therapy can be repeated later in those who fail after an initial response.

7. Requests may be considered for continued treatment during a treatment period or for resumption at a later date if satisfactory results have not been obtained, if compelling evidence of medical necessity is presented.

   Note: The generally accepted dosage is 2-4 units per kilogram of body weight. The patient is usually started with a low dose of Botulism Toxin Type A (10 units) and the accepted maximum dosage per site is about 25 units. It is generally agreed that once a maximum of 25 units per site has been reached and there is no response, the treatment should be discontinued. The treatments may be resumed at a later date. With response, the effect of the injections generally lasts for 3 months at which time the patient may need repeat injections to control the spastic condition. It is usually considered not medically necessary to give Botulinum Toxin Type A injections for spastic conditions more frequently than every 90 days.

8. For severe Primary Hyperhidrosis the following criteria must be met:

- Conservative measures have failed
- There is significant functional impairment (i.e. scores of 3 or 4 on the Hyperhidrosis Disease Severity Scale (HDSS) who are not responsive to or cannot tolerate topical agents. (3 = underarm sweating barely tolerable/frequency interferes with daily activities; 4= underarm sweating intolerable/always interferes with daily activities)
- Medical complications such as skin maceration with secondary infection exist

Botulinum Toxin A is supplied in vials. Each vial contains 100 units. Code J0585 should be billed with the number of units that represents the dosage given. However, due to the short life of the Botulinum Toxin, Medicaid will reimburse for the full 100 unit vial. Documentation in the patients medical record must show the exact dosage of the drug given and the exact amount of the discarded portion of the drug.

***Botulinum Toxin B (Myobloc) will be reviewed on a case by case basis.**

MONTANA
Department of Public Health & Human Services

Documentation Requirements

Documentation must state the signs and symptoms and diagnosis that support the need for service.

Documentation must include the following elements:

- Support the medical necessity of the BotulinumToxin injection
- Diagnosis
- A statement that traditional methods of treatments have been tried and proven unsuccessful
- Dosage and frequency of the injections
- Support the clinical evidence of the injections
- Specify the sites injected

_____

Signature of Medical Director Effective Date